EXHIBIT F

U.S. FOOD & DRUG ADMINISTRATION

CDRH Message: Medical Devices Supply Issue and Potential Shortages as Sterigenics Willowbrook Product Sterilization Facility Ceases Operations

Supply issues can lead to shortages of medical devices—and can pose a threat to public health by delaying or disrupting critical care for patients. Mitigating product supply issues and working to prevent patient harm from device shortages are important to the U.S. Food and Drug Administration (FDA).

The FDA's Center for Devices and Radiological Health (CDRH) is aware that on February 15, 2019, the Illinois Environmental Protection Agency (EPA) issued a Seal Order to stop the Sterigenics facility in Willowbrook, Illinois, from sterilizing medical products and other products with ethylene oxide. Learn more about the Environmental Protection Agency's assessment of Sterigenics Willowbrook Facility on EPA.gov.

Medical devices account for over 90 percent of the products that the Sterigenics Willowbrook facility sterilizes. The FDA is reaching out to medical device manufacturers to understand which manufacturers are affected by the cessation of operations at this sterilization facility. At this time, the FDA believes that more than 100 manufacturers and hundreds of devices may be affected.

Currently, the FDA is not aware of any device shortages. In case of a potential shortage, the FDA identifies strategies that will limit or mitigate patient impact due to device supply interruptions. The FDA also reaches out to device manufacturers who might not be affected by an issue to determine their availability to ramp up production and potentially mitigate a shortage.

Report Sterilization Site Changes to the FDA

- **Premarket Approval (PMA) Holders:** If you are a PMA holder affected by the cessation of operations at the Sterigenic's Willowbrook facility and you are planning to use an alternative facility to sterilize your products, you should submit a 180-day site change supplement. However, the FDA intends to review such PMA supplements within 30 days. The FDA recently issued the final guidance, Manufacturing Site Change Supplements: Content and Submission, that PMA holders can refer to for more information about site change supplements. If you have questions about your PMA device or need help with submitting a site change supplement, contact CDRHPremarketProgramOperations@fda.hhs.gov.
- **510(k) Holders:** If you are a 510(k) holder affected by the Sterigenic's Willowbrook

facility shutdown and you are planning to use an alternative ethylene oxide sterilization facility, submitting a new 510(k) is typically not required. You should document qualification activities supporting this change in your internal files. However, the FDA recommends that affected 510(k) holders refer to the FDA's guidance, Deciding When to Submit a 510(k) for a Change to an Existing Device: Guidance for Industry and Food and Drug Administration Staff when determining if a new 510(k) is required.

Report a Medical Product Supply Issue or Shortage

Planning for and preventing device supply shortages is an important responsibility. The FDA can help anticipate, prevent or mitigate future shortages by working with device manufacturers that voluntarily provide us with information on potential product supply issues. Learn more about how to report a medical product shortage or supply issue.

Questions?

If you have questions about medical device supply issues or shortages, contact Deviceshortages@fda.hhs.gov.

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